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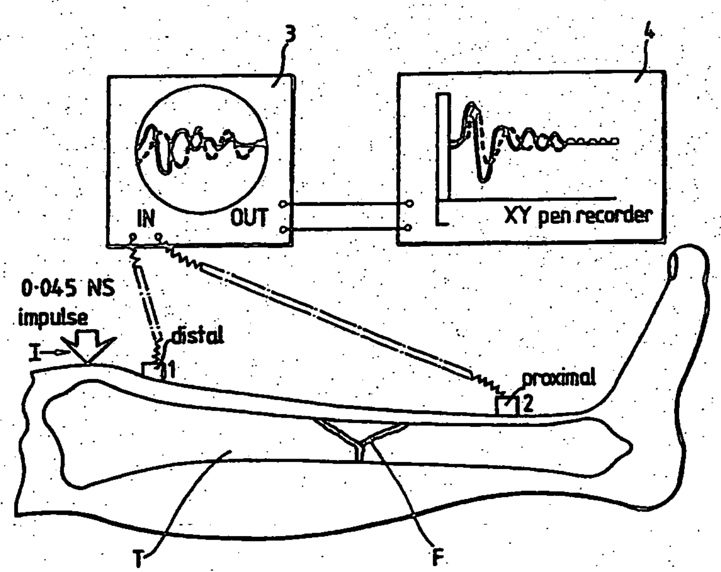
(54) Method and apparatus for assessing the structure and mechanical integrity of osseous systems

(57) A method and apparatus for assessing the mechanical and structural integrity of osseous systems for example the progress to completion of fracture union of a fractured bone. The method involves stimulating the bone to set up vibrations in the bone and then monitoring the resulting vibrations from the bone in such a way that an accurate assessment of the integrity of the bone can be made. This may be done by either stimulating the bone by mechanical impulse and detecting the changes in transmission of vibration from one point to another in the bone, or stimulating the bone with a sinusoidal wave form and monitoring the changes in resonant frequencies of the bone parts under investigation.

The disclosed invention has the attributes that it yields a measure of the mechanical state of bone and that measure is quantitative. Moreover it yields data of similar quality whether the bone is intact, disrupted, healing or the site of an implant, splint or prosthesis of whatever material, and has applications as a research tool or clinical monitor of skeletal changes.

Fig. 1.



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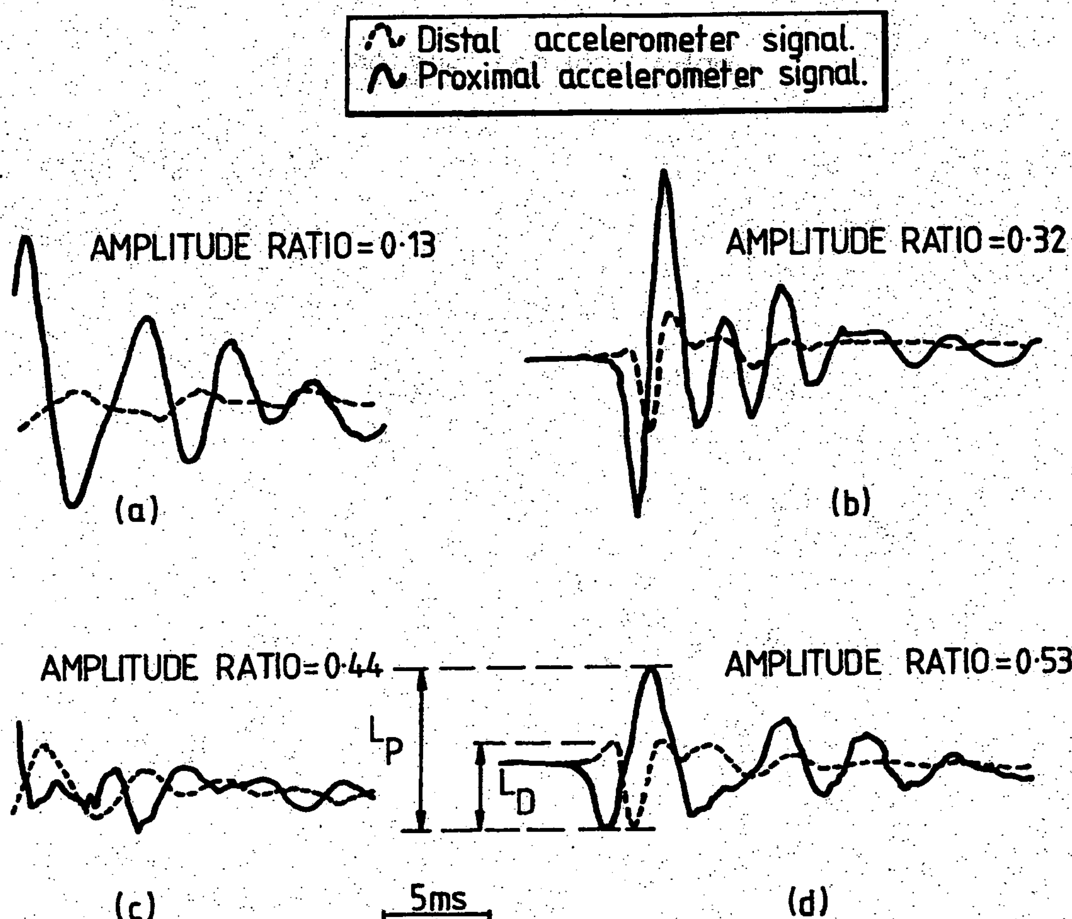

Distal accelerometer signal.
Proximal accelerometer signal.
AMPLITUDE RATIO = 0·13
(a)
AMPLITUDE RATIO = 0·32
(b)
AMPLITUDE RATIO = 0·44
(c)
L_P
L_D
5ms
AMPLITUDE RATIO = 0·53
(d)

Fig. 2.

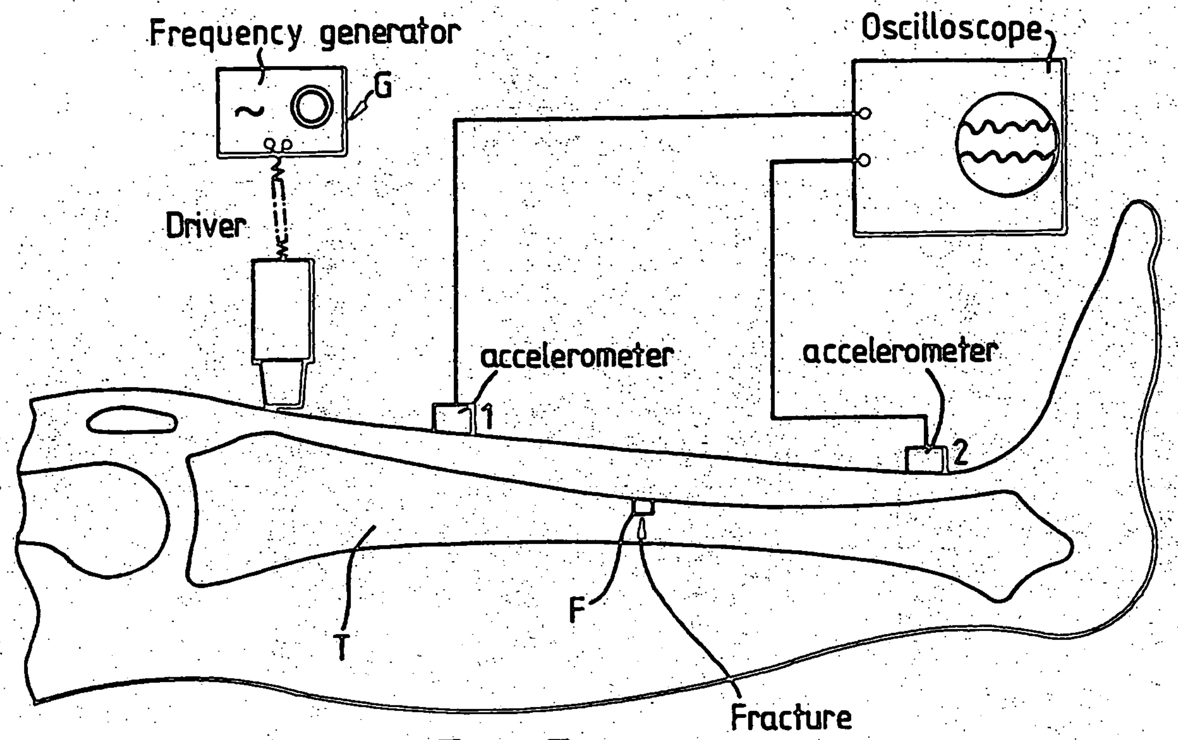

Frequency generator
G
Driver
Oscilloscope
accelerometer
1
accelerometer
2
T
F
Fracture

Fig. 5.

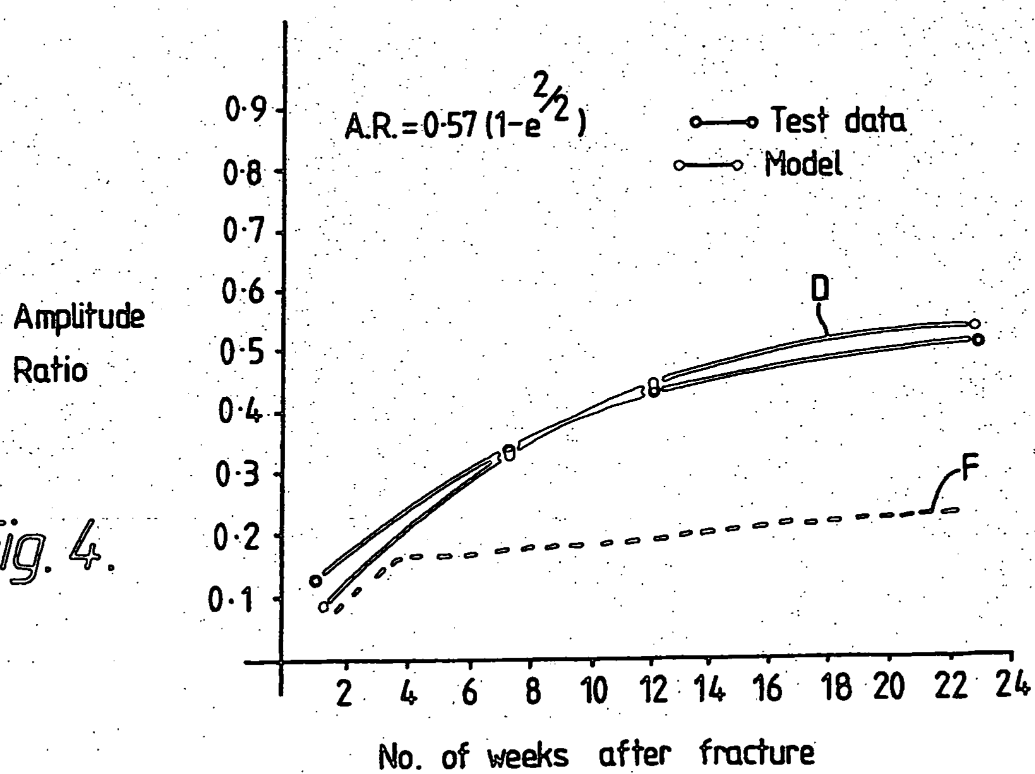
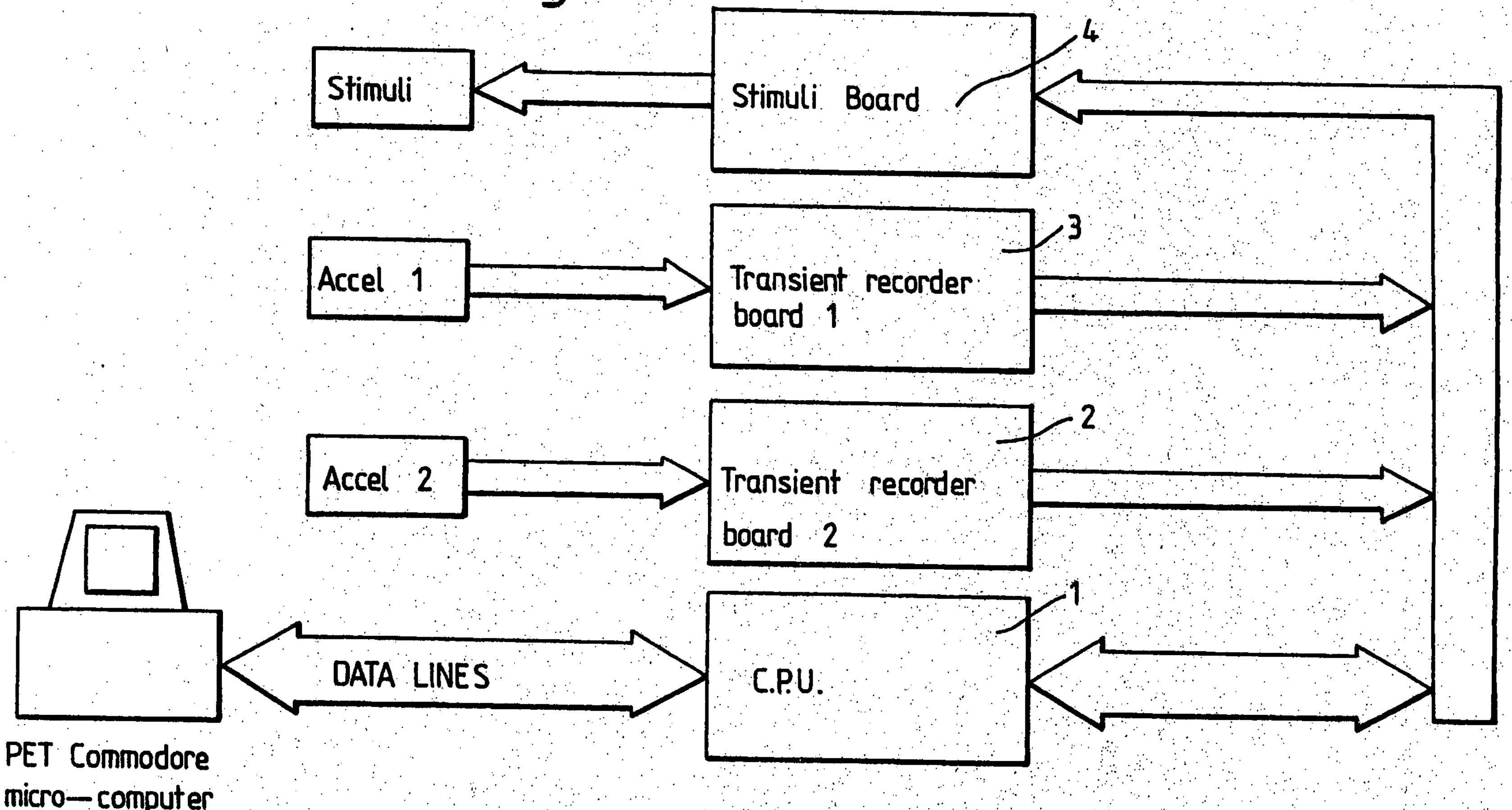

A.R.=0·57 (1−e^2/2)
Test data
Model
Amplitude Ratio
0·9
0·8
0·7
0·6
0·5
0·4
0·3
0·2
0·1
D
F
2
4
6
8
10
12
14
16
18
20
22
24
No. of weeks after fracture

Fig. 4.

Fig. 7.



Schematic diagram of fracture monitor

With this method the step of obtaining the ratio between the respective vibratory signals from the two vibratory responding means, or the difference in natural mode frequency, cancels out extraneous and unwanted factors (such as limb dimensions) which would otherwise complicate the measurement assessment of the progress of bone fracture union, and secondly, the weighting or preloading of the responding means diminishes the excessive damping effects on the vibratory signals caused by transmission of the signals through the skin tissue surrounding the fractured bone.

It has been found preferable to weight or preload the vibratory responding means, advantageously in the form of accelerometer, by an amount which is related to the thickness of the soft tissue between the bone and the measuring device, and having a lowest threshhold value of preload sufficient to overcome the damping effects of the tissue.

To avoid having to employ weighted or preloaded accelerometer probes in both the above forms of bone stimulus to monitor vibratory response, Doppler ultrasonic sound detectors may be used, and the maximum Doppler shift frequencies above and below the fracture obtained to provide an assessment of union.

According to another aspect of the invention there is provided a method of assessing bone fracture union, comprising applying vibratory stimulus to a fractured bone, and monitoring vibratory response from the bone thereby to determine progress to complete fracture union.

Brief description of the drawings

The invention will now be described by way of example with reference to a preferred embodiment of the invention illustrated in the accompanying drawings wherein

Figure 1 is a schematic illustration of suitable apparatus for assessing progress of bone fracture union according to the invention;

Figure 2 shows representative vibratory signal recordings taken from a group of patients with tibial shaft fractures at various stages of healing using the apparatus of Figure 1;

Figure 3 is a histogram of the amplitude ratios of vibratory signals obtained with the apparatus of Figure 1, from thirty normal tibiae;

Figure 4 is a graph of time-after-fracture plotted against amplitude ratio comparing those tibiae that went on to satisfactory union with tibiae that did not progress to satisfactory union; and

Figure 5 is a schematic illustration of an alternative suitable apparatus for assessing progress of bone fracture union according to the frequency mode aspect of the invention.

Best modes of carrying out the invention

Apparatus for assessing the progress of fracture union of a skeletal element, in this case the human tibia, is shown in Figure 1.

It comprises a pair of accelerometers 1 and 2 shown mounted on the anteromedial subcutaneous surface of a tibia T respectively to either side of a tibial fracture F. In the operational example shown the accelerometer 1 is positioned 60 mm distal to the tibial tubercle, whilst the accelerometer 2 is 60 mm proximal the medial malleolus.

To set up the required vibration in the tibia an impluse I of 0.045 Ns may be applied to the tibial tubercle, by means not shown, and the resulting vibrational effects in the tibia are displayed on an oscilloscope 3 coupled to the accelerometers, the oscilloscope 3 being set simultaneously to display two traces respectively representative of the signals from the accelerometers 1 and 2. An x-y pen recorder 4 is connected to the oscilloscope 3 to provide a permanent record of the vibratory signal.

To counteract the effects of skin thickness, each accelerometer 1 and 2 is preloaded with a vertical force to such a degree that the obtained vibratory signal is comparable with a reference vibratory signal which would be obtained with the accelerometers positioned directly on the fractured bone. It has been shown that this is met when the preload is within the range 3.2 to 6 Newtons, and the required value within this range in any given case is directly proportional to skin thickness.

To test the clinical accuracy of the apparatus of Figure 1, a group of 20 patients, with unilateral diaphyseal fractures in the tibia, and normal contralateral limbs were monitored with the apparatus to assess successful fracture union.

Four typical waveform traces obtained from four patients over a period of time, from a few hours from initial injury up to six months later, are shown in Figure 2(a) to 2(d), Figure 2(a) being that from the left tibia of a 27 year old male after two weeks, Figure 2(b) from the left tibia of a 17 year old male at two weeks and corresponding to a showing of moderate callus on the radiograph, Figure 2(c) the right tibia of an 80 year old male at twelve weeks and corresponding to tenuous radiographical union, and Figure 2(d) the right tibia of a 22 year old male at eighteen weeks, clinically and radiographically solid. All the fractures were managed nonoperatively and went on to satisfactory union.

Each Figure 2(a) to 2(d) shows a dual trace of a damped waveform, that in dotted outline being the response from the distal accelerometer 2. The other damped waveform trace, in full outline, is the response from the proximal accelerometer 2 which is nonvariable and normal in all cases, that is normal with respect to that trace which would be obtained with the proximal accelerometer from a non-fractured tibia.

In another mode of carrying out the invention the skeletal element is stimulated by a sinusoidal waveform and the first mode natural frequency of the skeletal part under study is measured directly and used to form a quantitative measure against which to assess the state of bone fracture union.

Thus in comparison to the first above-described mode of carrying out the invention, where the amount of energy transmitted along a bone is related to its structural and mechanical integrity, the second mode is based on the premise that the natural frequency of a discrete skeletal element is corrupted if that element's structural integrity is compromised, and the part then exhibits one or more different natural frequencies.

To drive the bone at its natural frequency, an electro- mechanical vibrator is applied to the skin and is driven by a sine wave generator whose output is variable in frequency, and determinable, so that the skeletal element can be driven at its natural frequency whatever that may be.

Figure 6 is a schematic illustration of an alternative suitable apparatus for assessing progress of bone fracture union, according to the frequency mode aspect of the invention. It comprises a frequency generator G for vibrating the human tibia T, by application of a continuous vibration to the tibial tubercle. A first bone vibratory responding means, in the form of an accelerometer, is applied 60 mm from the tibial tubercle and a second bone vibratory responding means is applied to the subcutaneous surface 60 mm from the medial malleolus, that is to either side of a fracture F in the tibia T.

Each bone vibratory responding means is coupled to an oscilloscope from which both signals from the accelerometers can be displayed. For the tibia, the first mode natural frequency for both proximal and distal fragments thereof is determined by stimulating the tibial tubercle at various frequencies, and observing that frequency at which the displayed sinusoidal trace of each accelerometer signal reaches its maximum amplitude.

When the tibia is fractured the two traces on the oscilloscope show that the measured natural frequency is different in the proximal and distal fragments, and that the proximal fracture has the higher frequency. The healing tibia may be visualised as two major fragments vibrating independently at first but with an interface zone which gradually becomes stiffer. As healing progresses the length of the vibrating system is effectively increased and this has the effect of depressing the natural frequency of the vibrating fragments.

The mean fall in frequency difference as the tibia heals, correlates well with clinical and radiological evidence of union, but is evident long before either of these current clinical techniques are helpful in the assessment of fracture healing.

Calculation of this mean difference over a period of time forms an accurate means for assessing bone fracture union and when the difference is extremely small or non- existent fracture healing can be said to have taken place, the natural frequency of the tibia at that time corresponding to the first mode natural frequency of an intact tibia.

A block diagram of a system for processing the data received from the accelerometers using the impulse mode of the invention is given in Figure 6. The heart of the system is a microcomputer board offering four analogue- to-digital converter inputs, and a number of digital outputs which may be used for circuit-control purposes. The inputs and outputs are all activated by computer software, which has been written specifically to perform the procedure described above.

The operating sequence is as follows: a digital trigger pulse from the computer is sent via an interface circuit to a solenoid-actuated piston. The piston is released, and impinges onto the tibia giving an impulsive stimulus of defined value. The resulting vibrations within the tibia are detected by accelerometers 1 and 2 (Bruel & Kjaer, type 4369), appropriately positioned on either side of the fracture site. The accelerometers convert these vibrations into low-level electrical signals, which are then amplified by instrumentation Amplifiers ICl and ICla. Provision is made in these circuits for the cancellation of offset potentials, and for the adjustment of amplifier gain in order to compensate for any imbalance in the sensitivities of the transducers.

The amplified accelerometer signals are then fed to the peak detector circuits, IC2 and IC3 for Accelerometer 1, IC2a and IC3a for Accelerometers 2. IC2 (IC2a) captures and stores the maximum positive value of the vibration transient, and holds it ready for use by the channel 1 (1a) analogue-to-digital converter. Similarly, IC3 (3a) captures the maximum negative amplitude of the same transient for use by the Channel 2 (2a) analogue-to-digital converter. The computer now allows conversion to take place; the timing of this process is software-controlled, so that conversion occurs within a few milliseconds of the detection of the transient peaks, in order to minimise errors due to the inevitable decay of voltage at the output of the detectors.

The values resulting from the conversion process are stored by the computer as four variables. A simple arithmetic sequence now calculates the peak-to-peak amplitude of vibration transient from each accelerometer, and determines the ratio of the two amplitudes for display as the required result of the test. Finally, the computer generates a pulse which resets the outputs of all the peak detectors to zero, in readiness for the next test.

RAM, general control register and the PIA for read/write operations. Writing to any other channel card register will disable the channel and enable the new channel.

The next register on a channel card is the GENERAL REGISTER. The general register is addressed in the range DD00 to DDFF. The general register can only be read after the channel has been enabled, however it can be written to at any time. This ability to write to the general register at any time means that all channel cards will receive the same information at the same time. The channel register allows individual control of the output lines, the general register allows coordinated control of several cards at the same time.

The last input output device on the card is a 6821 PIA. This is addressed in the range DE00 of DEFF. The PIA can only be written to or read after the channel has been enabled. The first and second locations make up the data registers of the PIA. The third and fourth locations are the control registers. This is to allow the PIA to be treated as a sixteen bit device. Data can be written to it as either eight bits, from the A or B registers or as sixteen bits from the D, X or Y registers etc.

The address lines are linked to the PIA in a non standard arrangement to give this type of access.

A0 is linked to RS1

A1 is linked to RS0

The two interrupt lines IRQA and IRQB are linked to the system bus IRQ line and to the channel register.

The current prototype cards do not have full address decoding so that the registers on the channel cards are duplicated throughout their address range.

Several channels are reserved for system applications. The reserved channel numbers are 0 and F0 to FE. One channel, 0, is reserved as a dummy, a write to it will disable all channels without causing control problems. All other channel numbers are to be used as access control to the individual cards.

There are four onboard I/O devices. These are used primarily for communications and control. The devices are the 6840, the 6850, the 68488 and a six bit, output only, latch linked to a row of LEDs. The latch can be used by the CPU to signal any errors found during a self test. One bit of the latch is reserved to allow the operating software to switch the system from a GPIB slave unit to a GPIB master unit. This option can be ignored and the CPU board hard wired as a master or a slave. A master can take control of the bus and use it to report the results or to take control of any other slave devices on the bus, e.g. there are many x- y plotters on the market with IEEE GPIB interfaces and such a plotter could be used to plot the result.

The onboard input/output devices only occupy the top thirty two bytes of the I/O block. The remaining section can be used for external input/output devices. These must all be addressable in the top section of the I/O block.

The above methods for assessing the mechanical properties of a healing tibia have involved the use of skin mounted accelerometers to detect the transmission of externally induced vibrations along the tibia. The effect of soft tissue between the accelerometers and the tibia attenuates the received signals, and careful placement and preloading of the transducers is necessary to obtain reproducible results.

An alternative technique, based upon Doppler ultrasound, to measure tibial vibrations may be employed, which is independent of the skin thickness and involves no preloading of the accelerometers. Ultrasound striking a moving target will be reflected back to the transmitter changed in frequency by an amount given by:

$$f_D = 2f_S\, v / c$$

where f_D is the change in frequency (Doppler shift),

f_S is the frequency of the incident sound,

v is the velocity of the moving target, and

and c is the speed of sound in the medium between source target (approximately $1500\,m\,s^{-1}$).

If the target is vibrating sinusoidally then its velocity can be written as

$$v = a_o w \sin wt$$

where a_o is the displacement of the target at a time t. The maximum velocity is given by

$$v_{max} = a_o w = 2\pi f a_o$$

where f is the frequency of vibration of the target. Hence

$$f_D \max = \frac{2f_s v_{max}}{c}$$

and so

$$f_D \max = \frac{4\pi f f_s a_o}{c}$$

Hence by measuring the maximum Doppler shift frequency the amplitude of vibration may be determined. By suitable choice of f_s, f and amplitude of vibration of target a value for f_D in an acceptable range can be obtained.

16. A method as claimed in claim 15 wherein said ultrasound probe is coupled to the skin surface by a suitable water based gel.

17. Apparatus for assessing the mechanical and structural integrity of osseous systems substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

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